UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/096,500	06/12/98	ASHKENAZI	A P1110P1

HM22/0716

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EXAMINER	
KAUFMAN, C	
ART UNIT	**PAPER NUMBER**
1646	5

DATE MAILED: 07/16/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/096,500	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	Claire M. Kaufman	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *12 June 1998* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-54* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) ☐ Notice of References Cited (PTO-892)
15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
17) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☐ Other:

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1646.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14, 21, 26, 27, 49, 51 and 52 drawn to Apo-2DcR polypeptide, chimeric polypeptide, and article of manufacture comprising the polypeptide, classified in class 530, subclass 350.

II. Claims 15-34 and 50-52, drawn to antibody, hybridoma cell line and article of manufacture comprising the antibody, classified in class 530, subclass 387.1.

III. Claims 35-44, drawn to nucleic acid, vector, host cell and process of producing the encoded polypeptide, classified in class 435, subclass 69.1.

IV. Claims 45-46, drawn to transgenic animal, classified in class 800, subclass 2.

V. Claims 47-48, drawn to knockout animal, classified in class 800, subclass 2.

VI. Claims 53-54, drawn to method of modulating apoptosis, classified in class 514, subclass 12.

The inventions are distinct, each from the other because of the following reasons:

The polypeptides of Group I are related to the antibodies of Group II by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the polypeptide and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are structurally and functionally different, and the polypeptide can be used for another and materially different process other than for production of the antibody, such as to assay or purify the natural ligand of the polypeptide, or in assays for the identification of agonists or antagonists of the polypeptide.

The nucleic acid of Invention III is related to the polypeptide of Invention I by virtue of encoding the same. The nucleic acid has utility for the recombinant production of the protein in a host cell, as recited in claim 44. Although the nucleic acid and polypeptide are related since the nucleic acid encodes the specifically claimed polypeptide, they are distinct inventions because the polypeptide product can be made by another and materially different process, such as by synthesis or purification from the natural source. Further, the nucleic acid may be used for processes other than the production of the polypeptide, such as nucleic acid hybridization assay for detection of tissue specific mRNA presence or to identify related nucleic acids.

The polypeptide of Group I and polynucleotide of Group III, which are themselves distinct, are related to the transgenic and knockout animals of Groups IV-V in that the animals express the polypeptide or have an altered gene encoding the polypeptide and because those animals express the nucleic acid or comprise an altered nucleic acid. Nevertheless, the inventions are distinct because the nucleic acid can be used for a materially different purpose such as for the *in vitro* production of the protein or for identification of related nucleic acids by hybridization screening. The inventions are further distinct because the polypeptide can be expressed by other means, for example by transfection of an *in vitro* host cell with the encoding nucleic acid. Also the polypeptide can be used for another and materially different process such

as in the production of an antibody or affinity purification of the natural ligand of the polypeptide.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Invention I can be used in a materially different process such as in the production of an antibody or affinity purification of the natural ligand of the polypeptide.

The nucleic acid of Group III is related to the antibody of Group II by virtue of encoding the polypeptide which is the cognate antigen of the antibody. However, the nucleic acid is distinct from the antibody for the reasons that the polypeptide and antibody are distinct inventions. Additionally, the nucleic acid can be used for a process other than production of the polypeptide/antigen, such as nucleic acid hybridization assay, and is structurally and functionally different from the antibody.

The antibody of Invention II is unrelated to the transgenic or knockout animal of Inventions IV-V, which are themselves distinct, as well as to the method of Invention VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody is structurally and functionally different than either animal and cannot be used in or produced by the method of Invention VI. The transgenic animal of Invention IV is related to the knockout animal of Invention V in that the transgenic expresses a non-altered or fully functional nucleic acid encoding the Apo-2DcR polypeptide, while the knockout animal has an altered gene and, in accordance with the art-accepted meaning of knockout, would not express a fully functional Apo-2DcR polypeptide. These animals have different functions and comprise different Apo-related nucleic acids. Therefore, the animals of Inventions IV and V are distinct.

The nucleic acid of Invention III is related to Invention VI by encoding the polypeptide which can be used in the process. However, the inventions are distinct because the nucleic acid can be used for a process other than production of the polypeptide, such as nucleic acid hybridization assay, and cannot directly be used in the claimed method.

The method of Invention VI is unrelated to the transgenic or knockout animal of Inventions IV-V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the animals cannot be used in or produced by the method of Invention VI.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, and the search required for each Invention is not coextensive with another, restriction for examination purposes as indicated is proper.

A telephone call was made to Diane L. Marschang on July 14, 1999 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Friday from 8:00AM to 4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.

Patent Examiner/Art Unit 1646

July 15, 1999